Data sharing in orthodontic research

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MANUSCRIPT

The ultimate goal of orthodontic research is the effective dissemination of new findings to the wider community. However, studies published in scientific journals are often compromised by incomplete reporting that can minimise their potential impact by compromising appropriate critical appraisal by the reader, replication by other research teams or inclusion in meta-research. Typical examples include studies that fail to report baseline characteristics of included subjects and standard deviations for continuous outcomes; or those that report percentages of patients with an event of interest at multiple time-points, without reporting the effective sample at each time-point.

From the reader's point-of-view, not having all the required information compromises our ability to critically appraise the research findings in terms of magnitude, applicability and, ultimately, clinical relevance.

From the researcher's point-of-view, a lack of data needed to include a study in a meta-analysis means that this study will ultimately not contribute to the evidence-base. The meta-analyst retains the option to contact a corresponding author and request the missing data, but unfortunately in the vast majority of cases the authors either do not respond at all or they cannot provide the data for a variety of reasons. Moreover, it is important to note that although raw measurements taken during a study and the calculated descriptive statistics are objective data, any statistical analysis used to draw inferences between two or more variables always carries a degree of subjectivity. In other words, the same data might be analysed by two persons differently, without either necessarily being wrong.

Finally, from a *patient's* point-of-view, all those who agree to take part in clinical research do so on the basis that this research is carried out and reported to the highest standard and will further existing knowledge in the field, ultimately benefitting the patient community through more effective and efficient patient care. When we, even inadvertently, hold back on such potentially useful information we do our patients a great disservice, by not fulfilling our ethical obligations as researchers.

There is a growing movement in the scientific community to encourage reproducibility and transparency practices within the scientific community, including public access to protocols and raw data, the conduct of replication studies, systematic integration of evidence in systematic reviews and the documentation of funding and potential conflicts of interest (Iqbal et al. 2016).

What can be done

The International Committee of Medical Journal Editors (ICMJE) believes there is an ethical obligation to responsibly share data generated by clinical research, and especially interventional clinical trials because patients have put themselves at risk. The ICMJE proposes to require authors to share with others the de-identified individual-patient data underlying the results presented in any article (including tables, figures, and appendices or supplementary material) no later than 6 months after publication. The data underlying the results are defined as the individual-patient data required to reproduce the article's findings. Therefore,

ICMJE requires the following as conditions for consideration of publication of a clinical study report in its member journals: As of 1 July 2018 manuscripts submitted to ICMJE journals that report the results of clinical research must contain a data sharing statement (Taichman et al. 2017); and clinical trials that begin enrolling participants on or after 1 January 2019 must include a data sharing plan in the trial registration (including their ClinicalTrials.gov protocol), including ethical committee approval and patient informed consent. Many journals have now adopted data sharing policies and whilst these are not yet strongly enforced, others maintain more stringent requirements for data sharing (Alsheikh-Ali et al. 2012).

Points to consider

Just as patient confidentiality must be protected (through de-identification of the dataset) so must the reasonable rights of researchers and sponsors be protected. The ICMJE has proposed the following measures for this: ICMJE editors will not consider data deposition in a repository as prior publication; the authors of secondary analyses must attest that this use is in accordance with the terms (if any) agreed to upon their receipt; authors of secondary analyses must reference the source of the data using a unique DOI of a study dataset to provide appropriate credit to those who generated it (and allow searching for the studies it has supported); and authors of secondary analyses must explain completely how theirs differs from previous analyses, if it does. In addition, those who generate and then share clinical trial data-sets deserve substantial credit for their efforts. Efforts are currently placed towards devising appropriate credit or recognition systems in the academic community (Ioannidis et al. 2014).

Whom does this concern?

Editors of scientific journals in orthodontics can actively encourage or even demand data sharing through the 'Instructions for Authors' website and their online manuscript submission system. This can be done by requiring authors to submit a data statement, including what data from the study are available, who can access the data (and how) and optimally, how to replicate the study results. This may be through uploading a dataset in an online open repository (Harvard Dataverse, Dryad, Mendeley Data, Zenodo) during manuscript submission, with the authors then providing the data set's unique Digital Object Identifier (DOI) received from the repository, which is published together with the paper. Associate editors and peer-reviewers need to be aware of the advantages of data sharing and check if this has been covered in the submission. Researchers submitting to journals should also be aware that editors may take into consideration data sharing statements and data availability when making editorial decisions. *Finally, funding agencies* and *scientific societies* funding orthodontic research can include data sharing as requirement for all grantees.

Sharing primary data will increase confidence in the conclusions of clinical studies, generate new hypotheses, make the most of what may be learned from each study, and enable independent confirmation of results, which is an essential tenet of the scientific process. In the end, data sharing helps fulfil our moral

obligation to study participants, thereby benefiting, patients, researchers, clinicians, funding agencies and ultimately, society.

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Table 1. List of general medicine and orthodontic journals and their policy regarding data sharing of research data

Journal	Data availability encouraged	Mandatory
Annals of Internal Medicine	-	Data statement published in paper (before References) Willingness to provide data for randomised trials
British Medical Journal	Data statement published in paper (before References)	Data availability for randomised trials on request
Journal of Clinical Epidemiology	Upload dataset via submission system to a repository Linking dataset's DOI in the submission system Data-availability banner in the published paper Data statement published in paper (before References)	-
New England Journal of Medicine	-	Data availability for microarray studies
Journal of the American Medical Association	Data statement published in paper (before References)	
Lancet	Data statement including dataset's DOI published in paper (Methods section)	-
Nature	-	Data statement published in paper (Methods section) and data availability in repository
PLOS journals	Data statement strongly recommended	-
American Journal of Orthodontics and Dentofacial Orthopedics	Linking dataset's DOI in the submission system Data-availability banner in the published paper Data statement encouraged	-
European Journal of Orthodontics	-	-
The Angle Orthodontist	-	-
Journal of Clinical Orthodontics	-	-
Journal of Orofacial Orthopedics	Repository deposit encouraged	-
Korean Journal of Orthodontics	-	-
Orthodontics & Craniofacial Research	(only mention)	-
Journal of Orthodontics	(only mention)	-
Journal of the World Federation of Orthodontists	Linking dataset's DOI in the submission system Data-availability banner in the published paper Data statement encouraged	-
Orthodontic Waves	Linking dataset's DOI in the submission system Data-availability banner in the published paper Data statement encouraged	-
Dental Press Journal of Orthodontics	-	-

Table 2. List of funders for which clinical trial archiving is required (Hahnel, 2015)

Funder	When	Country
AHRC	At the earliest possible opportunity	UK
Austrian Science Fund	Immediately after publication of results	Austria
Bill and Melinda Gates Foundation	Immediately after publication of results	USA
Biotechnology and Biological Sciences Research Council (BBSRC)	Must be archived within 3 years after project completion	UK
Canadian Institutes of Health Research (CIHR)	Immediately after publication of results	Canada
Cancer Research UK	Immediately after publication of results	UK
Department for International Development (DFID)	Must be archived within 12 months after project completion	UK
Economic and Social Research Council (ESRC)	Must be archived within 3 months after project completion	UK
Engineering and Physical Sciences Research Council (EPSRC)	At the earliest possible opportunity	UK
Fondazione Cariplo	Not specified	Italy
Genome Canada	Immediately after publication of results	Canada
Gordon and Betty Moore Foundation (GBMF)	At the earliest possible opportunity	USA
Heart and Stroke Foundation of Canada (HSF)	Immediately after publication of results	Canada
Higher Education Authority (HEA)	Within a reasonable time after completion of the work	Ireland
Howard Hughes Medical Institute (HHMI)	Immediately after publication of results	USA
Marie Curie Cancer Care	Immediately after publication of results	UK
Medical Research Council (MRC)	Within a reasonable time after completion of the work	UK
Michael Smith Foundation for Health Research (MSFHR)	Immediately after publication of results	Canada
National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs)	Not specified	UK
National Institutes of Health (NIH)	Within a reasonable time after completion of the work	USA
Natural Environment Research Council (NERC)	Within a reasonable time after completion of the work	UK
Nuffield Foundation	Must be archived within 1 year after project completion	UK
Ontario Institute for Cancer Research (OICR)	At the earliest possible opportunity	Canada
Országos Tudományos Kutatási Alapprogramok (OTKA)	Not specified	Hungary
Vetenskapsrådet	Within a reasonable time after completion of the work	Sweden
Wellcome Trust	Immediately after publication of results	UK
World Bank	At the earliest possible opportunity	United States